AMENDMENT TO _____

OFFERED BY M__. _____

At the end of subtitle B of title VI, insert the following:

SEC. 614. REPORT ON ENSURING QUALITY, SAFETY, AND CONTINUED EFFECTIVENESS OF DEVICES THAT HAVE BEEN SERVICED.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report on how the Food and Drug Administration intends to ensure the quality, safety, and continued effectiveness of devices (as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301(h))) with respect to which servicing (as defined in subsection (c)) has been performed by any entity engaging in such servicing.

(b) CONTENTS.—The report submitted under subsection (a) shall contain—

(1) the status of, and findings to date with respect to, the notice entitled ''Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third- Party Entities and Original Equipment Manufacturers; Request for Comments'' published by the Food and Drug Administration on April 25, 2016 (81 Fed. Reg. 24041 et seq.), including how the Food and Drug Administration intends to define the specific activities performed on a device by the manufacturer of the device or other entities;

(2) a description of the statutory or regulatory authority of the Food and Drug Administration used to oversee and regulate servicing conducted with respect to devices;

(3) details on how the Food and Drug Administration intends to protect the public health by ensuring consistent quality, safety, and continued effectiveness of devices with respect to which servicing has been performed by any entity engaging in such servicing;

(4) information on how the Food and Drug Administration can better understand the device servicing industry, including the size, scope, location, and composition of entities performing such serv-

icing and the rate of adverse events related to such servicing;

(5) information regarding the current regulation by states, the Joint Commission, or other regulatory bodies of servicing conducted with respect to devices by all entities, including original equipment manufacturers, third party entities, and hospitals; and

(6) any additional information determined by the Secretary (acting through the Commissioner) to be relevant to ensuring the quality, safety, and continued effectiveness of devices with respect to which servicing has been performed, including whether additional Federal statutory authority is necessary to ensure such quality, safety, and continued effectivness.

(c) SERVICING DEFINED.—In this section, the term ''servicing'' includes, with respect to a device, refurbishing, reconditioning, rebuilding, remarketing, remanufacturing, repairing, or other servicing of the device by a person other than the manufacturer of the device.